IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SEPRACOR INC., Plaintiff, v. DEY, L.P., and DEY, INC. Defendants.	C.A. No. 06-113 (JJF) C.A. No. 06-604 (JJF) CONSOLIDATED
SEPRACOR INC., Plaintiff, v. BARR LABORATORIES, INC., Defendant.	C.A. No. 07-438 (JJF)

SEPRACOR'S OPENING CLAIM CONSTRUCTION BRIEF

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347

Attorneys for Plaintiff Sepracor Inc.

OF COUNSEL:

Joseph M. O'Malley, Jr.
Bruce M. Wexler
PAUL, HASTINGS, JANOFSKY &
WALKER LLP
75 East 55th Street
New York, NY 10022

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NATURE AND STAGE OF THE PROCEEDING

Plaintiff Sepracor Inc. ("Sepracor") filed these patent infringement suits under the Hatch-Waxman Act against Dey, L.P., Dey, Inc. (collectively "Dey"), and Barr Laboratories, Inc. ("Barr") after Dey and Barr filed Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of Sepracor's highly successful medication for reversible obstructive airway disease (*e.g.*, asthma and chronic bronchitis), Xopenex® inhalation solution. The active ingredient in Xopenex® is a chemical compound known as levalbuterol hydrochloride. In these consolidated actions, Sepracor sued Dey and Barr for infringement of five patents directed to methods of treating individuals using levalbuterol hydrochloride: U.S. Patent Nos. 5,362,755 (the "'755 patent"), 5,547,994 (the "'994 patent"), 5,760,090 (the "'090 patent"), 5,844,002 (the "'002 patent"), and 6,083,993 (the "'993 patent") (collectively the "Sepracor patents").[1] Sepracor submits this brief in support of its constructions of the disputed claim terms of those patents.[2]

SUMMARY OF THE ARGUMENT

Sepracor's constructions of the disputed claim terms are based on the plain language of the claims and are consistent with the patent specifications and file histories. Dey's and Barr's constructions, however, seek to redefine the language of the claims and ignore well-established claim construction canons that do not permit the importation of limitations from patent specifications, file histories, or extrinsic sources into the claims.

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[1] Copies of the Sepracor patents are attached as Exhibits 1-5 to the accompanying April 10, 2008 Declaration of Preston K. Ratliff II.

[2] Sepracor sued Breath Limited, another ANDA applicant, for infringement of these same five patents in the District Court of Massachussets, *Sepracor Inc. v. Breath Limited*, C.A. No. 06-10043-DPW. On March 27, 2008, Judge Woodlock conducted a *Markman* hearing to construe some of the same claim terms at issue here. A ruling on those claim construction issues is expected in May.

The Sepracor patents are method-of-use patents directed to treating individuals using levalbuterol to reduce the undesirable "side effects" associated with administration of racemic albuterol, a form of albuterol containing a mixture of the isomers of albuterol.[3] Dey and Barr improperly seek to add limitations to the claims to specify and unduly limit which "side effects" are reduced. The plain language of the claims, as well as the patent specifications and file histories, however, demonstrate that the "side effects" encompassed by the claims are not limited to the particular side effects cited by Dey and Barr. Indeed, the flaw in their approach is apparent. If Dey's constructions were accepted, the patents would exclude "side effects" that are specifically identified in the patent specification. Similarly, if Barr's constructions were accepted, the patents would not only exclude such "side effects," but also would exclude a demonstrated "side effect" (airway hyperreactivity) that the U.S. Patent Office specifically recognized in granting the patents. Not surprisingly, black letter claim construction law does not permit these illogical results.

Further, Dey seeks to redefine the plain and ordinary meaning of several claim terms. For example, Dey asserts that the term "reversible obstructive airway disease" should be construed to mean "asthma," even though asthma is just one form of reversible obstructive airway disease. Dey's proposed construction flies in the face of the plain language of the claim and finds no support in the intrinsic evidence.

STATEMENT OF FACTS

Sepracor's method-of-use patents teach that, prior to Sepracor's discoveries, a drug known as albuterol was commonly used to treat bronchial spasms associated with reversible

[3] Isomers are molecules having the same chemical formula, but with their atoms arranged in space as non-superimposable mirror images of one another.

obstructive airway disease, asthma being one form of this broader disease class.[4] [*See, for example*, Exh. 1, '755 patent, Col 1:20-22.][5] Albuterol is believed to relax smooth muscle tissues, which results in a dilation (or opening) of the bronchials so that the human body can take in oxygen. [Exh. 1, '755 patent, Col. 1:18-20.]

Prior to Sepracor's discoveries, the form of albuterol used to treat individuals with respiratory disorders, such as asthma, was a racemic mixture. [Exh. 1, '755 patent, Col. 1:25-26.] Racemic mixtures are a mixture of isomers called enantiomers. [Exh. 1, '755 patent, Col. 1:25-27.] Enantiomers are structurally identical compounds that differ only in that one enantiomer is a mirror image of the other and the mirror images cannot be superimposed. [Exh. 1, '755 patent, Col. 1:27-30.] In nature, molecules that have enantiomers always exist as the racemic mixture. To obtain an isomer separate from its enantiomer, a deliberate chemical separation of the isomers must be undertaken.

Racemic albuterol is a mixture of two isomers, R(-) albuterol (or levalbuterol) and S(+) albuterol.[6] [Exh. 1, '755 patent, Col. 2:9-15.] The Sepracor inventors discovered that undesirable side effects associated with the administration of racemic albuterol could be reduced by administering to a person only the optically pure R(-) isomer of albuterol (substantially free of the S(+) isomer.) [Exh. 1, '755 patent, Col. 2:4-15.]

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4 Bronchial spasms are life-threatening situations that occur when certain smooth muscle tissues in the lungs constrict, severely reducing oxygen intake.

5 "Exh. __" refers to exhibits attached to the accompanying Ratliff Declaration.

6 The isomers of enantiomeric pairs are distinguished by the direction that they rotate polarized light: "(+)" for dextrorotatory enantiomers, and "(-)" for levorotatory enantiomers. For a further background discussion of enantiomers, *see*, *e.g.*, *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 348 F. Supp. 2d 713, 720-21 (N.D. W.Va. 2004), *aff'd*, 161 F. App'x 944 (Fed. Cir. Dec. 19, 2005).

This result was very surprising and contrary to conventional wisdom. For years, racemic albuterol was considered safe and effective and was administered to patients on the belief that the S(+) isomer was "inert," *i.e.*, it was thought to cause no side effects. Given this view in the field prior to Sepracor's inventions, there was no reason to undertake the burden and expense of isolating the R(-) isomer and then administering only that isomer to a patient. Having discovered that administration of optically pure R(-) isomer reduces the side effects associated with the administration of racemic albuterol, Sepracor developed this isomer into its Xopenex® line of respiratory drug products, the first of which were approved by the FDA on March 25, 1999.

Racemic albuterol is presently sold in a cheap, generic form. Despite the availability of this product, Xopenex® (formulations of the R(-) isomer of racemic albuterol) has been commercially successful, with U.S. sales in 2007 on the order of a half-billion dollars. Sepracor's introduction of Xopenex® products, and the reduced side effects associated with these products, has thus led many doctors to prescribe the more expensive single enantiomer form, levalbuterol, over the racemic form.

Sepracor's method-of-use patents are all based on the same original application, U.S. application no. 07/461,262 (the "'262 application"), filed on January 5, 1990, and thus share the same written description.[7] Each patent is directed to the treatment of individuals with respiratory disorders using the optically pure R(-) isomer of racemic albuterol. The common patent specification makes plain that the inventions relate to a reduction of any side effects associated with administration of racemic albuterol, and not just the specified examples

[7] The only difference between the written descriptions of the method-of-use patents is the listing of applications to which each new patent claims priority based on the prior granted method-of-use patent.

mentioned therein. [*See, for example*, Exh. 1, '755 patent, Col. 2:4-9 ("The present invention relies on . . . the R(-) enantiomer of albuterol to provide relief from bronchial disorders, while simultaneously reducing undesirable side effects, ***for example***, central nervous system stimulatory effects and cardiac disorders, commonly experienced by albuterol users.")][8]

ARGUMENT

A. Claim Construction Standards

Claim construction is a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 116 S. Ct. 1384 (1996). "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc*., 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Claims "are generally given their ordinary and customary meaning." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The Federal Circuit has made clear that "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1313.

To determine the "ordinary and customary" meaning of a claim term, courts first examine the intrinsic evidence which consists of the language of the claims, the specification, and the prosecution history. *Phillips*, 415 F.3d at 1315 (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998) ("The best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history."). Indeed, "[t]he claims, specification, and file history, rather than extrinsic evidence,

[8] Emphasis in the quoted material is added unless otherwise noted.

constitute the public record of the patentee's claim, a record on which the public is entitled to rely." *Vitronics*, 90 F.3d at 1583. If claim construction is not founded on this public record, the public notice function of patents would be undermined. *Phillips*, 415 F.3d at 1319 (citing *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995)).

"First, and most importantly, the language of the claim defines the scope of the protected invention." *Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 619-20 (Fed. Cir. 1995). The terms of a claim are generally given their ordinary and customary meaning, unless the patent and prosecution history expressly indicate that the inventor used the terms differently. *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387 (Fed. Cir. 1992).

After consideration of the claim language itself, the claims are construed according to the patent specification. "For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims." *Markman*, 52 F.3d at 979. Where the patentee gives a term a certain meaning in the specification, that meaning will apply when interpreting the term as used in the claim. *See ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1579-80 (Fed. Cir. 1988). Although a patentee may give terms in a patent special meaning, it is improper for a court to redefine claim language if there is no clear evidence that the inventor was acting as his own lexicographer. *Wyeth v. Impax Labs., Inc.*, 526 F. Supp. 2d 474, 479 (D. Del. 2007) (*quoting Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("a patentee may choose to be his own lexicographer and depart from the ordinary and plain meaning words, 'as long as the special definition of the term is clearly stated in the patent specification or file history.'")); s*ee also Lucent Techs., Inc. v. Extreme Networks, Inc.*, 367 F. Supp. 2d 649, 668-69 (D. Del. 2005) (refusing to further interpret the phrase "identification of a source" based on a particular type of

source used in the preferred embodiment of the specification); *Purdue Pharma, L.P. v. F.H. Faulding and Co.*, 48 F. Supp. 2d 420, 435 (D. Del. 1999) (construing claims based on their "ordinary and plain meaning" to refer to individual patients and declining to read an "average" limitation into the claim where the patentee did not include either the term "average" or "mean"); *Astrazeneca AB v. Mutual Pharm. Co., Inc.*, 221 F. Supp. 2d 535, 544 (E.D. Pa. 2002) ("in order to demonstrate that the inventor chose to be his own lexicographer, the specification must clearly express an intent to redefine the ordinary term.").

In construing the claims based on the specification, *Phillips* also cautions that courts must "avoid the danger of reading limitations from the specification into the claim." *Phillips*, 415 F.3d at 1323. "The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims." *Id.* at 1312 (quoting *Markman*, 52 F.3d at 980); s*ee also Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1211 (Fed. Cir. 2007) (holding that the district court erred in limiting the term "pharmaceutically acceptable polymer" to hydrophilic, water-soluble compounds selected from a list in the written description). The *Phillips* court also acknowledged "the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice." *Phillips*, 415 F.3d at 1323. The court further warned against restricting the claims only to specific embodiments of the invention described in the specification and noted that the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Id.* at 1323 (citing *Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Comm'n*, 383 F.3d 1352, 1366 (Fed. Cir. 2004)).

The prosecution history, which represents the "undisputed public record" of patent proceedings, "should also be used when considering the legal issue of proper claim construction." *Amhil Enters. Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1559 (Fed. Cir 1996); *Phillips*, 415 F.3d at 1317 ("Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent."). A court using the prosecution history in its claim construction analysis must give "appropriate weight" to the prosecution history "in light of the statutes and policies that inform patent law." *Phillips*, 415 F.3d at 1324. Courts, however, should not use the prosecution history to rewrite the plain language of the claims. *See Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) ("This court, however, repeatedly and consistently has recognized that courts may not redraft claims, whether to make them operable or to sustain their validity."); *Quantum Corp. v. Rodime, Plc*, 65 F.3d 1577, 1584 (Fed. Cir. 1995) ("it is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims.").

Although courts can always rely on experts to explain the background technology at issue, explain how the invention works, or to ensure that the court's understanding of technical aspects of the patent is consistent with that of a person of ordinary skill in the art (*Phillips*, 415 F.3d at 1318), "[i]n most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence." *Vitronics*, 90 F.3d at 1583. If after examining all the intrinsic evidence, further clarification of a claim term is required, the Federal Circuit has "authorized district courts to rely on extrinsic evidence, which 'consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.'" *Phillips*, 415 F.3d at 1317 (quoting *Markman*, 52 F.3d at 980).

The Federal Circuit has noted, however, that extrinsic evidence is generally less reliable than the patent itself and the prosecution history in construing claim terms because it is not part of the patent and was not created at the time of the patent prosecution to explain the patent's scope and meaning. *Phillips*, 415 F.3d at 1318. The *Phillips* court also recognized another serious issue with extrinsic evidence:

> [T]here is a virtually unbounded universe of potential extrinsic evidence of some marginal relevance that could be brought to bear on any claim construction question. In the course of litigation each party will naturally choose the pieces of extrinsic evidence most favorable to its cause, leaving the court with the considerable task of filtering the useful extrinsic evidence from the fluff. *Id*.

It is well-settled law that validity issues should not be considered during claim construction and therefore have no place in a Markman brief or hearing. *See Markman*, 52 F.3d at 986, *citing Intervet Am., Inc. v. Kee-Vet Labs., Inc*., 887 F.2d 1050, 1053 (Fed. Cir. 1989) (matters which address claim validity are not relevant to claim construction and interpretation); *Mass. Inst. of Tech. v. ImClone Sys., Inc.*, 498 F. Supp. 2d 435, 439-40 (D. Mass. 2007) (refusing to address the defendant's invalidity and infringement arguments during the Markman stage of the proceedings).

B. Claim Construction Of The '755 Patent

Sepracor's constructions rest firmly on the plain language of the claims, and are consistent with the intrinsic evidence (patent specification and prosecution history).

Claim 1 of the '755 patent reads:

> A method of treating asthma in an individual with albuterol, while reducing side effects associated with chronic administration of racemic albuterol, comprising chronically administering to the individual a quantity of an optically pure R(-) isomer of albuterol sufficient to result in bronchodilation while simultaneously reducing undesirable side effects, said R isomer being substantially free of its S(+) isomer. [Exh. 1, '755 patent, Col. 4:6-13.]

1. "while reducing side effects associated with chronic administration of racemic albuterol"

Sepracor's Construction	Dey's Construction	Barr's Construction
The side effects are those associated with chronic administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	The side effects are limited to beta-adrenergic side effects directly caused by the S(+) isomer of racemic albuterol.	The side effects are limited to the side effects specifically identified in the patent specification at column 3, lines 28-31.

The parties dispute whether the "side effects" referred to in this claim term broadly mean the side effects associated with racemic albuterol, or are limited to a particular set of side effects. Sepracor notes that Dey and Barr cannot even agree on a narrowing construction of this plain claim language.

A review of the claim language itself makes plain that the term "side effect" is broad and can constitute any side effect associated with chronic administration of racemic albuterol. [Exh. 1, '755 patent, Col. 4:6-13.] This is consistent with the written description which, during the ten times it uses the term "side effects," never once restricts its scope. In fact, the illustrative examples discussed in the written description demonstrate that the term "side effects" is not limited to a particular set of side effects:

> The present method provides a safe, effective method for treating asthma while reducing undesirable side effects, ***for example***, **tremor, nervousness, shakiness, dizziness and increased appetite, and particularly, cardiac arrythmia,** typically associated with beta-adrenergic drugs. [Exh. 1, '755 Patent, Col. 1:56-61.]

The '755 patent written description does not limit the "side effects" which are reduced as a result of practicing the invention. To the contrary, the use of the term "for example" clearly indicates that "side effects" were not intended to be limited to the particular side effects disclosed therein.

[*See also* Exh. 1, '755 patent, Col. 1:61-63: "In children, side effects ***such as*** **excitement, nervousness and hyperkinesia** are reduced when the pure isomer is administered," Col. 2:6-9: "while simultaneously reducing undesirable side effects, ***for example***, **central nervous system stimulatory effects and cardiac disorders,** commonly experienced by albuterol users," and Col. 3:28-31: "These side effects ***include*** **central nervous system effects, *such as* tremor, nervousness, shakiness, dizziness and increased appetite, and cardiac effects, *such as* cardiac arrythmia**."]

Further, the prosecution history makes plain that the term "side effects" is broad in scope and not limited to the examples referenced in the patent specification. For example, the inventors made patentability arguments based on, among other things, avoidance of a side effect that was not specifically enumerated in the specification -- namely, avoiding airway hyperreactivity (a phenomenon where continued use of the drug results in a less effective response). [Exh. 6, May 12, 1994 Amendment at p. 4.] The inventors argued that, although avoidance of airway hyperreactivity was not specifically identified in the patent specification, it was a side effect that reasonably flowed from the disclosure of avoiding side effects. [*Id.*] The U.S. Patent Office agreed. [Exh. 7, Examiner's Amendment/Reasons for Allowance at 2-3.] This demonstrates that the term "side effects" is broad and is not limited to any particular set of side effects. Indeed, this exchange reinforces that the patent specification, in listing illustrative examples of certain side effects, did not circumscribe the scope of the "side effects" covered by the claims. It is improper for Dey and Barr to seek a claim construction that would exclude a meaning to which the inventors and the U.S. Patent Office agreed during patent prosecution. *Phillips*, 415 F.3d at 1317 ("Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent.").

Dey argues that the term "side effects" should be limited to beta-adrenergic side effects directly caused by the S(+) isomer of racemic albuterol.[9] Dey's construction therefore would exclude a side effect associated with racemic albuterol unless it is a "beta-adrenergic" side effect "directly caused" by the S(+) isomer. The problem with Dey's argument is that it seeks to rewrite the patent claim in a way which differs from its plain language. The plain language of Claim 1 of the '755 patent states that the side effects are those "associated with chronic administration of racemic albuterol." [Exh. 1, '755 patent, Col. 4:7-8.] Racemic albuterol includes both the R(-) and S(+) isomers. Side effects associated with racemic albuterol can include those caused by the S(+) isomer alone, but can also be those side effects that are exacerbated relative to optically pure R(-) albuterol due to the manner in which the R(-) and S(+) isomers interact in racemic albuterol. Dey's construction is also inconsistent with the prosecution history. During prosecution of the '755 patent, the inventors explained that their invention was not limited to side effects directly caused by the S(+) isomer by using the conjunctive phrase "or":

> . . . Applicants' disclosure which teaches that undesirable side effects are associated with the ***racemic mixture or the <u>therapeutically inactive</u> isomer***, i.e., the S(+) isomer, of albuterol, but <u>not</u> with the R(-) isomer. [Exh. 8, July 14, 1992 Preliminary Amendment, pg. 3].

The inventors thus stated in no uncertain terms that the undesirable side effects are those that are associated with the ***racemic mixture*** (racemic albuterol) ***or*** the therapeutically inactive isomer, *i.e.*, the S(+) isomer, and not just those associated with the S(+) isomer. Dey's construction

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[9] The term "beta-adrenergic side effects" is a term coined by Dey. Sepracor's inventors never used this term in their patent specification or during prosecution of the Sepracor patents. It is unclear to Sepracor what this term even means. Dey's proposed construction would, in effect, require a secondary *Markman* hearing just to construe Dey's proposed construction.

therefore is contrary to the plain language of Claim 1 of the '755 patent, the specification, and the patent prosecution history.

Taking a different, but also incorrect, approach, Barr argues that the term "side effects" should be limited to the side effects specifically disclosed at column 3, lines 28-31 of the '755 patent. [Exh. 9, Barr's March 26, 2008 letter to Sepracor, pgs. 1-2.] In other words, Barr seeks to rewrite the patent claim to be limited to some -- but not all -- of the illustrative side effects identified in the patent specification. Barr's approach is contrary to black letter law that limitations from the patent specification should not be imported into the claim. *See Chef Am.*, 358 F.3d at 1374 ("This court, however, repeatedly and consistently has recognized that courts may not redraft claims, whether to make them operable or to sustain their validity."); *Quantum Corp.*, 65 F.3d at 1584 ("it is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims."). Barr's proposed construction is also flawed because, among other things, it would exclude side effects specifically identified in the patent specification at places other than column 3, lines 28-31, such as "excitement" and "hyperkinesia." [Exh. 1, '755 patent, Col. 1:61-62.] Moreover, Barr's proposed construction would exclude the side effect "airway hypereactivity" -- the side effect referenced by the patentee to further demonstrate the patentability of its claims during patent prosecution and relied on by the U.S. Patent Office in allowing the '755 patent to issue.

The plain language of Claim 1 of the '755 patent should control and nothing in the prosecution history of the '755 patent is inconsistent with or redefines that plain language.

2. "chronic administration" and "chronically administering to the individual"

Sepracor's Construction	Dey's Construction	Barr's Construction
plain meaning – to administer the drug to a human on a ***recurring*** basis to prevent or reduce the extent to which bronchospasms occur	means "prophylactic"	Barr does not dispute Sepracor's construction

Barr does not dispute Sepracor's claim construction.[10] That alone should raise doubt as to the reliability of Dey's proposed claim construction.

The plain meaning of this claim language supports Sepracor's construction. The plain meaning of "chronically administering to the individual" means administering the drug on a recurring basis to a human to prevent or reduce the extent to which bronchospasms occur. Sepracor's construction is also supported by the prosecution history. For example, during the prosecution of the '755 patent, Sepracor submitted a declaration from a medical doctor certified by the American Board of Internal Medicine in pulmonary disease, Dr. T. Scott Johnson. [Exh. 10.] Dr. Johnson, acting as a consultant to Sepracor, explained to the U.S. Patent Office how chronic treatment according to the invention is a recurring treatment:

> Albuterol is, in the presently claimed invention, intended to be administered to "an individual who has asthma" . . . . Since the patient has asthma (i.e. suffers from a disease state), and the treatment is to be prophylactic, treatment would have to be chronic. If the treatment were not chronic, cessation of administration might or might not lead to an immediate attack, but it would certainly lead to reestablishment of the disease condition. [Exh. 10, May 11, 1994 Declaration of Dr. Johnson, pgs. 2-3.]

[10] Sepracor provided Barr its construction of these disputed terms, and informed Barr that Defendant Dey has a different view on their construction. Barr has not taken issue with Sepracor's construction.

The clear import of Dr. Johnson's explanation is that chronic administration is recurring administration, since cessation of a recurring course of administration could lead to "reestablishment" of the disease.

Dey's construction seeks to improperly rewrite the terms "chronic" and "chronically" to mean solely treatment which is "prophylactic." And although "chronic" use can include prophylactic use (*i.e.*, use of the drug prior to the onset of an asthma attack), the term "prophylactic" is insufficient to describe this term by itself. Clearly, one prophylactic use, as Dr. Johnson explained and as common sense dictates, is insufficient to treat a disease state that will resume in the absence of recurring administration of the drug. The plain meaning of the term "chronic administration" connotes recurring treatment, not a single use, and not simply a prophylactic use.

Not only is Dey's proposed construction over-inclusive, in that it could embrace a single use not supported by the intrinsic record, it is under-inclusive as well, in that it excludes use of the drug beyond "prophylactic uses." In the same Johnson declaration, the applicant made clear that "chronic" use embraced uses of the drug beyond just prophylactic: "Thus the person of skill in the art would understand that the [patent] application was referring to chronic therapy when it speaks of either prophylactic ***or*** periodic administration." [Exh. 10, May 11, 1994 Declaration of Dr. Johnson, pg. 3.] By the use of the conjunctive term "or," it is clear that Dr. Johnson did not redefine the plain meaning of "chronic" to refer to solely "prophylactic" use. So, for example, if one used the drug on a recurring basis (*i.e.*, "periodically"), sometimes that use might be prior to the onset of an asthma attack (prophylactic use) or sometimes it might be after the onset of an attack (non-prophylactic). Either way, as long as the administration is recurring, that is "chronic" administration, as the plain meaning of the term suggests.

Moreover, the prosecution history of the Sepracor patents makes plain that the inventors did not consider the claim term "chronic" to simply mean "prophylactic." For example, in a June 9, 1995 Response, the inventors stated that "the reference to prophylactic treatment [in the patent specification] ***relates to*** chronic therapy." [Exh. 11, June 9, 1995 Response, pg. 3.] The fact that the inventors said that prophylactic treatment ***relates to*** chronic therapy rather than ***is*** chronic therapy is significant. Accordingly, the term "chronic" does not require any construction other than its plain meaning -- in this context to administer the drug to a human on a recurring basis to prevent or reduce the extent to which bronchospasms occur.

3. "while simultaneously reducing undesirable side effects"

Sepracor's Construction	Dey's Construction	Barr's Construction
The side effects are those associated with chronic administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	The side effects are limited to beta-adrenergic side effects directly caused by the S(+) isomer of racemic albuterol.	The side effects are limited to the side effects specifically identified in the patent specification at column 3, lines 28-31.

The dispute here is identical to that of disputed claim term 1 of the '755 patent, *i.e.*, whether the scope of "side effects" are limited to particular side effects. For the reasons stated above, this claim language should be construed to refer to any side effects associated with the chronic administration of racemic albuterol.

C. Claim Construction Of The '994 Patent

The disputes regarding the '994 patent claim terms are identical to those of the '755 patent, i.e., whether the term "side effects" is limited to particular side effects.

Claim 1 of the '994 patent reads:

> A method of treating an acute attack of asthma, while reducing side effects associated with the acute administration of racemic albuterol, comprising administering to an individual suffering from

> an acute attack of asthma a quantity of an optically pure R(-) isomer of albuterol sufficient to result in bronchodilation while simultaneously reducing undesirable side effects, said R isomer being substantially free of its S(+) isomer. [Exh. 2, '994 patent, Col. 4:4-11.]

1. "while reducing side effects associated with the acute administration of racemic albuterol"

Sepracor's Construction	Dey's Construction	Barr's Construction
The side effects are those associated with acute administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	The side effects are limited to beta-adrenergic side effects directly caused by the S(+) isomer of racemic albuterol.	The side effects are limited to the side effects specifically identified in the patent specification at column 3, lines 28-31.

The '994 patent, like all of the Sepracor method-of-use patents, derive from the same parent patent application. This Court should therefore construe "side effects" in the same manner as the '755 patent. *See NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 1174 (2006) ("Because [the] patents [in-suit] all derive from the same parent application and share many common terms, we must interpret the claims consistently across all asserted patents."); *Taltech Led. v. Esquel Enters. Ltd.*, 410 F. Supp. 2d 977, 983 (W.D. Wash. 2006) ("A court must interpret the claims consistently across all patents that derive from the same parent application and share many common terms.").

2. "while simultaneously reducing undesirable side effects"

Sepracor's Construction	Dey's Construction	Barr's Construction
The side effects are those associated with acute administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	The side effects are limited to beta-adrenergic side effects directly caused by the S(+) isomer of racemic albuterol.	The side effects are limited to the side effects specifically identified in the patent specification at column 3, lines 28-31.

The dispute here is identical to that of disputed claim term 1 of the '755 patent, *i.e.*, whether the scope of the side effects is limited to a particular set of side effects. For the reasons stated above, "side effects" should be construed to refer to any side effects associated with the acute administration of racemic albuterol.

D. Claim Construction Of The '090 And '002 Patents

The main dispute regarding the '090 and '002 patents concerns whether or not the terms "side effects" and "adverse effects" are limited in scope to a particular set of side effects. The disputed terms and proposed constructions are listed below.

1. "while reducing side effects associated with the administration of racemic albuterol" ('090 Patent)/ "while reducing the concomitant liability of adverse effects associated with racemic albuterol" ('002 Patent)

"while simultaneously reducing undesirable side effects" ('090 Patent)/ "while simultaneously reducing said adverse effects" ('002 Patent)

Sepracor's Construction	Dey's Construction	Barr's Construction
The side effects (or adverse effects) are those associated with the administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	The side effects (or adverse effects) are limited to beta-adrenergic side effects directly caused by the S(+) isomer of racemic albuterol.	The side effects (or adverse effects) are limited to the side effects specifically identified in the patent specification at column 3, lines 28-31.

These issues are identical to those discussed above regarding the '755 and '994 patents. For the reasons presented above, the term "side effects" (or "adverse effects") is broad and should be construed to refer to any side effects associated with the administration of racemic albuterol.

2. "inducing bronchodilation or providing relief of bronchospasm"

Sepracor's Construction	Dey's Construction	Barr's Construction
plain meaning – "bronchospasm" means a contraction of smooth muscle in the walls of the bronchi and bronchioles, causing narrowing of the lumen, which is not limited to bronchospasms associated with asthma	"bronchospasm" refers to bronchospasms associated with asthma only	Barr does not dispute Sepracor's construction

The term "bronchospasm" as used in the '002 patent should be given its plain and ordinary meaning. [*See, for example*, Exh. 12, Stedman's Medical Dictionary 25th Ed. at 214 defines the term "bronchospasm" as "contraction of smooth muscle in the walls of the bronchi and bronchioles, causing narrowing of the lumen."] Barr does not dispute Sepracor's construction.[11]

Dey, on the other hand, attempts to limit the term "bronchospasm" to bronchospasm associated with asthma. [Exh. 13, pg. 19.] Dey's proposed construction is not supported by the claim language, the specification, or prosecution history.

The claim language itself does not warrant Dey's proposed construction. For example, the inventors clearly knew how to limit claims to asthma, as many of the claims in the

[11] Sepracor provided Barr its construction of this disputed term, and informed Barr that Defendant Dey has a different view on the construction of this term. Barr has not taken issue with Sepracor's construction.

prior-issued method-of-use patents are so limited. *See Phillips*, 415 F.3d at 1315 ("Other claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term . . . Differences among claims can also be a useful guide in understanding the meaning of particular claim terms.") (internal citations omitted); *CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000) ("In the absence of any evidence to the contrary, we must presume that the use of . . . different terms in the claims connotes different meanings."). The inventors, however, chose not to include an "asthma" limitation in the claims of the '002 patent.

Moreover, the specification does not support Dey's proposed limitation of "bronchospasm" to that associated with asthma. The Summary of Invention section of the patent specification makes clear that asthma is exemplary of a bronchial disorder that the invention is designed to treat, but is not the only bronchial disorder that the R(-) isomer of racemic albuterol can treat:

> The present invention relates to a method of treating ***bronchial disorders***, ***such as*** asthma, in an individual, by administering to the individual an amount of optically pure R(-) albuterol which is active in bronchial tissue sufficient to reduce bronchial spasms associated with asthma while minimizing side effects associated with albuterol. [Exh. 4, '002 patent, Col. 1:46-51.]

In addition, the prosecution history supports construing "bronchospasm" consistent with its plain and ordinary meaning. The claim term "bronchospasm" first appears in the claims in the application which became the '002 patent. In adding new claims containing this term, the inventors explained that:

> In the parent application, 08/691,604, claims were allowed to a "***method of treating asthma***". New claims 13-22 relate to "a method for inducing bronchodilation or providing relief of ***bronchospasms***." [Exh. 14, April 21, 1998 Preliminary Amendment, p. 4.]

It is clear from the passage above that the inventors did not consider the term bronchospasm to be limited to treating asthma.

Further, when the inventors presented these new claims, they referenced page 3, lines 8-9 and page 5, lines 5-6 of the original specification for support[12]:

> The present invention relies on the bronchodilation activity of the R(-) enantiomer of albuterol to provide relief from bronchial disorders . . .
>
> * * *
>
> optically pure R(-) isomer of albuterol given by inhalation one or more times per day will be adequate in most individuals to produce the desired bronchodilation effect.

Importantly, neither of these passages on which the inventors relied mentions "asthma." Instead, these passages refer to the relief of symptoms that can be associated with "bronchial disorders" generally.

Dey may argue that the Sepracor inventors acted as their own lexicographers, but the strict test for such an argument has not been met here. *See Vitronics*, 90 F.3d at 1582 (Fed. Cir. 1996) ("Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, ***as long as the special definition of the term is clearly stated in the patent specification or file history***."). As described above, there is no clearly stated evidence in the intrinsic record that the Sepracor inventors intended to act as their own lexicographers and redefine the term bronchospasm to mean only those bronchospasms associated with "asthma."

[12] Exh. 14, April 21, 1998 Preliminary Amendment, p. 4.

Further, limiting the term "bronchospasm" to only bronchospasm associated with asthma would improperly limit the invention to an exemplified embodiment. *See Phillips*, 415 F.3d at 1323 (The Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.") Thus, the claim language, the specification, and the prosecution history each indicate that the term "bronchospasm" as used in the '002 patent should be construed consistent with the full plain and ordinary meaning -- bronchospasm associated with a bronchial disorder -- not just bronchospasm which is a symptom of asthma as Dey proposes.

E. Claim Construction Of The '993 Patent

Sepracor and Dey dispute the meaning of the following claim phrases of the '993 patent:

"treating bronchospasm in a patient with reversible obstructive airway disease" (Claim 1)

"preventing bronchospasm in a patient with reversible obstructive airway disease" (Claim 10)

Sepracor's Construction	Dey's Construction	Barr's Construction
plain meaning of the terms "bronchospasm" and "reversible obstructive airway disease"	"bronchospasm" refers to bronchospasms associated with asthma only; "reversible obstructive airway disease" means asthma	Barr does not dispute Sepracor's construction

The specific terms of the claim phrases in dispute are "bronchospasm" and "reversible obstructive airway disease." For the reasons discussed above, the Court should construe the term "bronchospasm" consistent with its plain meaning. Barr agrees.[13]

[13] Sepracor provided Barr its construction of these disputed terms, and informed Barr that Defendant Dey has a different view on their construction. Barr has not taken issue with Sepracor's construction.

With respect to the term "reversible obstructive airway disease," the Court should also construe this term consistent with its plain meaning, *i.e.*, a respiratory disorder such as asthma, chronic bronchitis, and emphysema. [*See for example*, Exh. 15, Lurie, A. et al., *Long-Term Management of Reversible Obstructive Airways Disease in Adults*, Lung, 168 Suppl:154-167, 154 (1990) which describes the claim term broadly as a respiratory disorder that include, for example, "asthma, chronic bronchitis, and emphysema."[14]]

Dey, on the other hand, attempts to improperly limit the phrase "reversible obstructive airway disease" to asthma. [Exh. 13, Dey Second Supplemental Interrogatory Response, pgs. 9-10.] There is nothing in the claim language, specification, or prosecution history that warrants limiting the claims to asthma. As discussed above, the common specification makes clear that asthma is an exemplary bronchial disorder, not the only bronchial disorder targeted by the invention. [*See* Brief at section D.2.] Limiting the phrase "reversible obstructive airway disease" to only asthma would improperly limit the invention to a specific embodiment. *See Phillips*, 415 F.3d at 1323 (The Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.")

It is clear from the prosecution history that inventors specifically chose to use the broader term "reversible obstructive airway disease" in the claims of the '993 patent instead of the narrower term "asthma." For example, in adding new claims containing the term "reversible obstructive airway disease", the inventors explained that:

---

[14] As with the term "bronchospasm," Sepracor does not suggest that the Court adopt this specific definition from an extrinsic source. Sepracor provides this definition only to demonstrate that the claim term "reversible obstructive airway disease" is not limited to asthma as Dey contends.

> In previous applications in this series, claims have been allowed to "a method of treating ***asthma***". . . and to "a method of treating ***an acute attack of asthma***" . . . Applicants respectfully submit that new claims 13-29 to "a method of treating ***bronchospasm in a patient with reversible obstructive airway disease***" and to "a method of ***preventing bronchospasm in a patent with reversible obstructive airway disease***" are allowable . . . . [Exh. 16, December 17, 1999 Preliminary Amendment, p. 5.]

The passage above demonstrates that the inventors did not consider the term "reversible obstructive airway disease" to mean "asthma." It would be improper for this Court to limit the claim to treating bronchospasm associated with "asthma," effectively ignoring the "reversible obstructive airway disease" language. Thus, this Court should construe "reversible obstructive airway disease" according to its plain and ordinary meaning, and should not impose extraneous and unsupported limitations to the claims.

CONCLUSION

For the foregoing reasons, Sepracor respectfully requests that the Court adopt its constructions of the disputed claim terms of the asserted patents.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs Louden

Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
klouden@mnat.com
Attorneys for Plaintiff Sepracor Inc.

OF COUNSEL:

Joseph M. O'Malley, Jr.
Bruce M. Wexler
PAUL, HASTINGS, JANOFSKY &
WALKER LLP
75 East 55th Street
New York, NY 10022

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2290694

CERTIFICATE OF SERVICE

I, hereby certify that on April 10, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Steven J. Balick
John G. Day
Tiffany Geyer Lydon
ASHBY & GEDDES

Richard Hermann
MORRIS JAMES LLP

I also certify that copies were caused to be served on April 10, 2008 upon the following in the manner indicated:

BY E-MAIL AND HAND DELIVERY

Steven J. Balick
John G. Day
Tiffany Geyer Lydon
ASHBY & GEDDES
500 Delaware Avenue, 8th Floor
Wilmington, DE 19801

Richard Hermann
MORRIS JAMES LLP
500 Delaware Avenue
Suite 1500
Wilmington, DE 19801

BY E-MAIL

Edgar H. Haug
Sam Desai
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151

Elizabeth A. Leff
FROMMER LAWRENCE & HAUG LLP
1667 K Street, N.W.
Washington, DE 20006

George C. Lombardi
Imron T. Aly
Elizabeth H. Erickson
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601

/s/ Karen Jacobs Louden
Karen Jacobs Louden (#2881)